REMARKS

Claims 66-67 are now pending following entry of this Amendment. Applicants reserve the right to pursue the subject matter of the cancelled claims in continuation applications.

Objections To The Claims

The objection to claims 45, 48, 50 and 51 is rendered moot by the cancellation of these claims without prejudice.

Rejections Under 35 USC §112, first paragraph

A. The rejection of claims 27-33, 36 and 42-59 as being non-enabled for the use of the term "homologue" is rendered moot by the amendments to the claims presented herein.

B. The rejection of claims 43-51 and 53-55 as failing to comply with the written description requirement is rendered moot by the amendments to the claims presented herein.

Rejections Under 35 USC §112, second paragraph

The rejections of claims 27-33, 36 and 40-65 under section 112, second paragraph for the recitations of "high stringency conditions", "the nucleic acid sequence that encodes SEQ ID NO:1", "first trefoil domain" and "second trefoil domain" are rendered moot by the amendments to the claims presented herein.

Rejections Under 35 U.S.C. 103

As newly added claim 66 is limited to polypeptide having an amino acid according to SEQ ID NO:1 and the glycosylation structure at Asn 15 that was previously recited in now cancelled claim 65, Applicants believe that all the obviousness rejections set forth on pages 6-14 of the present Office Action, with the exception of the rejection discussed in the following

paragraph, are rendered moot by the amendments to the claims presented since none of the other rejections were applied to now cancelled claim 65.

The single rejection which Applicants now address, as it might be applied against pending claims 66-67, is the rejection of claims 27, 29-31, 33, 40 and 60-65 over Tomasetto in view of Podolsky, Alberts, Hitzeman and Lodish as applied to claims 27, 29, 30, 40 and 60-62 and further in view of Onda, Stausberg and Gelfand.

The prior art is cited as teaching that it would be obvious to express an hSP polypeptide in yeast with a reasonable expectation of success (which Applicants dispute; see pages 7-10 of Amendment filed August 19, 2002) where the expressed polypeptide would be glycosylated at the Asn at position 15 and wherein the glycosylated form would comprise$(GlcNAc)_2(Man)_{10-15}$ because, relying on Lodish, two units of GlcNAc and 3 mannose are always found in N-linked oligosaccharides and N-linked oligosaccharides can have as many as 60 mannose residues (citing to Figure 16-27 of Lodish).

With all due respect, Applicants traverse this rejection.

Newly added claims 66-67 are limited to a specific polypeptide that has been described in structural terms as having SEQ ID NO:1 and a specific glycosylation structure at Asn 15 of SEQ ID NO:1. Thus, a prima facie case of unpatentability requires that the teachings of the prior art suggest the claimed polypeptide to a person of ordinary skill in the art.

Here, even assuming arguendo that it would be obvious to express an hSP polypeptide in yeast with a reasonable expectation of success, the claimed polypeptide has a specific glycosylation structure, $(GlcNAc)_2(Man)_{10-15}$, and there is nothing in the cited art that teaches that this specific glycosylation structure might be attached to the Asn 15 of SEQ ID NO:1 upon recombinant expression of that sequence in yeast.

In particular, while Figure 16-27 of Lodish teaches that typical asparagine-linked oligosaccharides have at least two units of GlcNAc, the Figure shows that 3 different types of N-linked oligosaccharides may exist:

1) N-linked high mannose oligosaccharide which has, in addition to two units of GlcNAc, up to 60 mannose residues in yeast;

2) N-linked complex oligosaccharide, which has two or more branches, each containing, in addition to two units of GlcNAc, at least one GlcNAc, galactose and sialic acid residue per chain; and
3) N-linked hybrid oligosaccharide, which contains in addition to two units of GlcNAc, one branch that has the complex structure of 2) and one or more branches having the high mannose structure of 1).

There is nothing in the cited art that teaches or suggests which of the 3 structures above might be attached to the Asn 15 of the claimed sequence (assuming it would be glycosylated at all) yet alone that if it was a high mannose structure according to 1) above, it would contain from 10-15 mannose residues as opposed to any other number of mannose residues from 3 up to 60. Thus, even assuming arguendo that one might express the cDNA of Tomasetto in yeast and that glycosylation at Asn 15 of SEQ ID NO:1 might occur, this does not mean that the claimed specific polypeptide was precisely envisioned and therefore obvious.

Accordingly, in view of the amendments to the claims presented herein and the above remarks, Applicants submit that added claims 66-67 are non-obvious over the cited art.

Obviousness-Type Double Patenting Rejection

The Examiner rejected claims 27-33, 36 and 40-65 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 and 10-13 of US Patent No. 5,783,416.

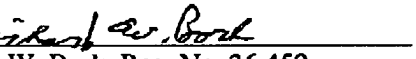
In reply, Applicants submit that they will submit an appropriate terminal disclaimer to obviate this rejection upon indication of allowable subject matter by the Examiner.

Attorney Docket No.: 3951.224-US
Serial No.: 09/528,644
Filed March 20, 2000

The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this paper or application.

Respectfully submitted,

Date: November 3, 2004



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